AHNS
Otobase

Clinical Trials Manual

Otobase software performance reports should be sent to:

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Contents

OTOBASE

Using Otobase in Multi-site Clinical Trials

This manual explains how to set up and conduct a multi-site clinical trial using the Otobase software program, and how to effectively use the program's features that support data collection, sharing and encryption.

Part 1

The Otobase method of data sharing

Sharing data in multi-center clinical studies presents a number of obstacles. Some are physical, such as collating the data, verifying that participants are filling in data completely, and checking for protocol violations. Some are more psychological, but no less important, such as allowing control of the data by the participants as opposed to a central collating authority.

Otobase has been designed to address these issues directly. Developed primarily as a research tool, this software supports multi-site trials with features that allow consistent data collection while preserving study subject confidentiality and data traceability.

Some of these features include:

- **Public/private key encryption**, giving study participants the confidence that shared data can be viewed only by someone they wish to view it, and allowing a central site to store backup copies of encrypted data sent by study participants as a hedge against data loss.
- **Checksums**, which detect the slightest change in transmitted data and make it virtually tamper-proof. Shared data exports can be limited to a few data fields during the initial phase of a study while documents containing only checksum information verify that a larger data set is actually being collected. Participants can later share the larger data set with the assurance of its integrity.

How this manual is organized

The Otobase clinical trials manual is divided into three parts.

If you wish, you can skip directly to Part 3 on Page 18, which gives step-by-step instructions for setting up a trial using the program's automated features. You will find separate sections for study coordinators and participants so that you only need to follow the specific directions for your given role in a trial. Those who would like an overview of the program's features and how they work together should read Part 1 first. If you would like to learn how to manually export and encrypt data in the special Otobase TRANSFER format, as well as manually decrypt and import the TRANSFER documents, you will find instructions in Part 2 starting on Page 8.

For a more comprehensive explanation of the full capabilities of the software to enter, retrieve and report data, as well as a reference to all menus, commands and data fields, please refer to the Otobase User Guide.

- **Study participant IDs**, allowing data to be merged from multiple sites without demographic identifiers, preserving subject anonymity while maintaining identification of data sources.

Otobase is also designed to help coordinate study activities, with data entry Checklists that ensure saved records meet study criteria, and modifiable staging, protocol and approved procedure lists that aid in consistent reporting. All of these features can be updated by a study coordinator and distributed to participants as computer files, by e-mail, or as downloads from the Web.

Setting up a trial using the automated features built into Otobase involves these main steps:

- Creating matching Clinical Group records for the study group.
- Assigning unique Study Participant IDs.
- Setting up data encryption and decryption.
- Defining study data to be exported.

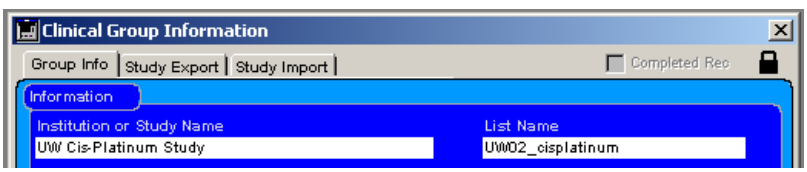
Part 1 will present an overview of each of these steps, as well as explain the unique Otobase Checksum mechanism.

Creating matching database records for the study group

Most of the important tools used to organize, share and protect data gathered in a trial are centered around the Clinical Group record.

A Clinical Group can be an institution, such as a hospital, or it can simply be a study. For example, a Clinical Group in Otobase could be a grouping of subjects who share something in common that researchers wish to study, such as the use of cis-platinum/5FU/ radiation to treat tumors or involvement in a p53 gene therapy trial.

When initiating a study, it is critically important that a study coordinator decide on a unique List Name for the group. In addition to identifying a Clinical Group, the List Name is used to automate encryption and e-mail exporting/importing features. To avoid conflicts with the



Clinical Groups that may already exist in a study participant's data file, the study's List Name needs to be unique. One of the best ways to ensure this is to create a name with a prefix, such as UW02_, which could stand for the initials of the study coordinator's institution and the year the study began (see List Name in picture above). It is also a good idea to use the same prefix in naming searches, exports and Checklists that are associated with the study to make

sure these will also be uniquely named and won't conflict with other such items in a participant's data file.

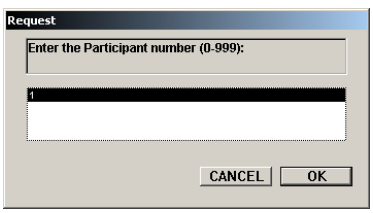
The best way to ensure that key information in the Clinical Group record is the same for all involved in a study is for the coordinator to create the initial record, then send the information to all participants so they can create a matching record.

For an explanation of how to set up the Clinical Group record, see Page 21.

Assigning unique Study Participant IDs

Otobase automatically generates an internal identification number each time a new record is created. These make it possible to mix data from multiple sites in a single database being used in a study. The Participant ID number and the related Study Participant ID are an integral part of this capability.

The first time you use the Otobase structure file with a newly created data file, you are asked to enter a Participant ID number between 0 and 999. Otobase uses this number as part of the internal ID numbers to identify and relate records in different tables.



For example, all subject-related records have a unique number in the Subject_ID field. Otobase uses the Participant ID as the last three digits of this subject identifier.

Because there is no way to guarantee that participants in a multi-site trial implemented their Otobase data files with unique Participant IDs, the study coordinator can assign Study Participant ID numbers that will be substituted for the last three digits of IDs in records exported for a trial. This is an automated function that is only available for data exports encrypted with a private key. The site coordinating a study will be able to decrypt the data and import it only if the Study Participant ID number and the associated public decryption key agree. This guarantees that only the participant authorized to use that Study Participant ID has submitted the data. For instructions on assigning these IDs, see Page 22.

Using encryption to protect shared data

Otobase's use of public/private key encryption allows participants in a geographically diverse study to share information over the Internet or via disk while protecting both the privacy of study subjects and the integrity of data.

Public/private key encryption, in which the encryption and decryption keys form a unique pair, is a powerful tool for proving the source of a message or data. The person sending data generates both a private and a public key, then encrypts the data with the private key and sends the encrypted data to the receiver. By a separate method, the sender needs to convey the public key to the receiver for use in decrypting the data. The receiver then uses the public

Background on Public/Private Key Encryption (1024 bit)

Data can be encrypted with different degrees of security. Simple encryption schemes involve use of a mathematical algorithm to encode messages and a single "key" for both coding and decoding. If you know the formula to encode the message and you know the encryption key, you can decode the message by reversing the process.

Public/private key encryption is much more sophisticated. A computer generates a paired encryption key and decryption key. Once a message is encrypted with the encryption key, the only way to decrypt the message is to use the paired decryption key. Even if the algorithm used to encrypt the message is known, having the encryption key does not help you. In fact the designation of "encryption" and "decryption" keys is deceptive since either key can be used in some schemes to successfully encrypt a message as long as its paired key is used to decrypt the message. To help distinguish between the actual roles in a key pair, the encryption key is called the "private" key and the decryption key is called the "public" key.

key and can read the decrypted data only if the proper private key was used to encrypt it. Thus the receiver knows for certain that the originator sent the data and, just as importantly, the originator cannot deny that he or she was the source for the data.

For an explanation of how to set up public/private key encryption, see "Setting up encryption" on page 23 and "Setting up decryption" on page 24. For an explanation of dual-key encryption, see "Background on Public/Private Key Encryption (1024 bit)" above.

Defining study data to be exported

At the heart of every joint research study is a definition of the data of interest. Otobase allows you to create Clinical Group Checklists, Searches and Exports so study participants can:

- Identify and control the entry of data pertinent to the study (Clinical Group Checklist).
- Retrieve any record in the database that fits the study definition (Clinical Group Search).
- Define exports for sharing the data with others involved in the study (Clinical Group Export).

Let's briefly examine each:

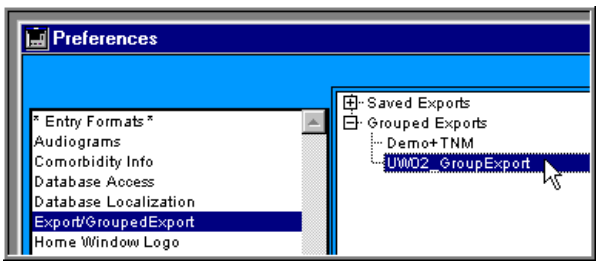
Clinical Group Checklists

Especially in the case of a clinical study, it is important to make sure saved records meet minimum criteria. To simplify and enforce this process, Otobase allows the administrator to create Checklists that review a data entry form when it is being saved, and prompt the user if any of the minimum information is missing. These Checklists can then be assigned to the Clinical Group so all members are screening their data using the same criteria. For instructions on creating a Sequential Search/Checklist, see Page 26.

Clinical Group Search

Once records are saved, retrieving them is a process of defining fields and/or values to look for, and then narrowing the search by looking for related records in other parts of the database. An entire chapter in the Otobase User Guide is devoted to this process (see Chapter 4, "Searching"). Once you have defined a search, you can save the search definition. The resulting Saved Search is the key building block of a Sequential Search, which can perform a series of Saved Searches within a single table of the database and then combine the results to create a final set of records meeting the combined criteria. The Clinical Group Search further automates the process by allowing you to define a Sequential Search of multiple tables that can find all data of interest to the study with one easy search. (see Page 26 for instructions on creating Sequential Searches).

Clinical Group Export



After you build the searches that will allow participants to find data of interest, exporting data involves searching for records, and then selecting the fields to be exported and an export format. To automate this process for a study, Otobase has a feature known as a Grouped Export. It is created from a series of Saved Exports in the same way that a Sequential Search is created from a series of Saved Searches. The steps involved in creating a Grouped Export can be found on Page 27.

Assigning the Checklist, Search and Export

After creating a Clinical Group Checklist, Search and Export, the study coordinator assigns them to the Clinical Group record (see "Assigning a Clinical Group Search and Export" on page 29 and "Assigning Checklists" on page 30). To share these "study tools" with participants, the study coordinator can export all three using a single menu item. Otobase creates a special document that bundles all three items into a single file and encrypts them using the coordinator's private key if data encryption has been set up for the trial. Participants who have received the public key from the coordinator and entered it in the study's Clinical Group form may then import the bundled Checklist, Search and Export definitions into their version of the database, and all three will be automatically decrypted (see "Exporting study tools" on page 31 and "Importing study tools" on page 35).

The Otobase TRANSFER file format

Otobase uses a special TRANSFER file format for sharing data between participants in a study. The TRANSFER files can be encrypted and decrypted, inspected for content before being imported into the receiver's database, and can include checksum data with or without the actual record data. To learn the steps involved in manually exporting data using the TRANSFER format, see Part 2 starting on Page 8.

Checksums

Checksums are an extremely helpful tool in verifying that the data sent from one computer arrives at another computer without being changed. In essence, checksums are a mathematical way of analyzing a data stream and reducing it to a single, representative long integer (+/- 2,147,483,647). The data stream is made up of data bits, each equal to 0 or 1. By processing a series of repeated calculations using a specially selected "polynomial," a computer can examine a data stream and detect the change in a single bit. In the case of multi-site clinical studies, checksums can also be used to make sure that subject data sent from various sites is never changed after first being collected.

Checksums are most often used in data transmission where a data stream is sent followed by its calculated checksum. The receiving computer calculates its own checksum on the data stream and compares it to the received checksum. If the two match, the data stream has remained unchanged during transmission and is therefore valid.

The same theory underlies the use of checksum calculations in Otobase for entire database records and exported data field subsets. All records or fields exported in a TRANSFER-type export document include their unique internal ID fields in addition to the requested export fields. Calculating a checksum on all of these fields virtually guarantees that a record or selected subset of data fields cannot be modified without changing the checksum. It is important to realize that subtle changes such as capitalizing a letter in a text field result in a completely different checksum calculation.

If checksums are used it is not even necessary for participating institutions or individuals to exchange the actual data until the conclusion of a study. Instead, a CHECKSUM-type export document can be exchanged with the coordinating institution. At the conclusion of the study the actual data can be exchanged and the checksums compared to verify that no data has been altered. For the steps in creating a CHECKSUM-type export, see Page 10. For a more detailed explanation of the theory behind checksums and their implementation, see Chapter 9 in the Otobase User Guide, "Database Design and Theory."

Part 2

Sharing data manually using special formats

Even though Otobase allows you to automate the sharing of data for a trial (see Part 3, "Setting up a trial using automated features" on page 18), it is useful to understand the manual procedures for exporting and importing data using the TRANSFER or CHECKSUM formats.

A TRANSFER document can only be read in another version of Otobase. This offers one level of security, and we will also explain how to encrypt a TRANSFER document to further protect the confidentiality of subject data.

For a more complete explanation of some of Otobase's other exporting and importing functions, see Chapter 5, "Exporting and Reporting," Chapter 7, "Administrator Functions," and Chapter 9, "Database Design and Theory" in the Otobase User Guide.

Selecting data for manual export

Exporting data manually is a process of searching for records, selecting an export format, then exporting the data. Follow these steps to select the data for export regardless of the format you will choose.

To select data for export

1. Select Reports > Export Data.
   The Search for Export form opens.
2. Create a set of records to export (see Chapter 4, "Searching," in the Otobase User Guide).
3. Drag the set of records to Drop Export Set.
   The Export Data form opens.

The Export Data form has two tab selections: Field Info and Export Format. Field Info allows you to choose specific fields to include in the export. Export Format allows you to select the format for export.

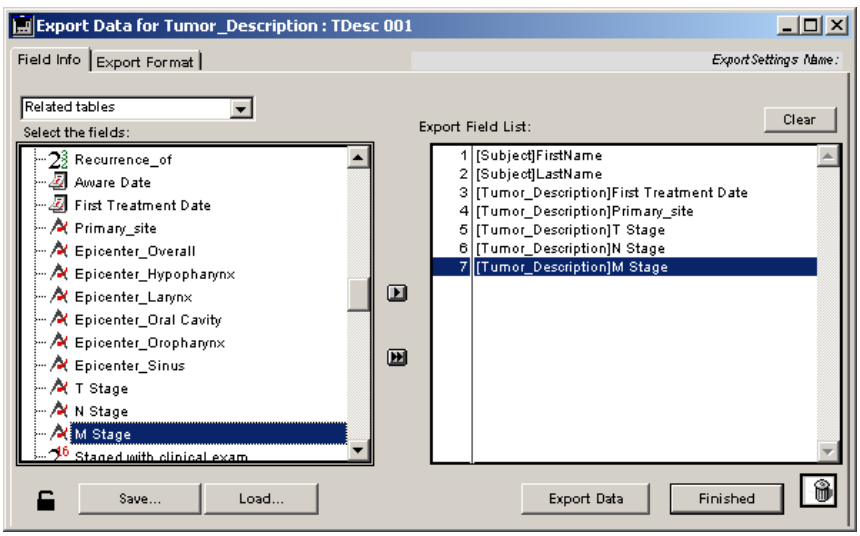
A pop-up above the field list controls the display of the data fields for export. To begin with, it reads "Master Table."

You can choose from two other options:

- "Master table, sorted" displays the data fields for the master table in alphabetical order.
- "Related tables" once again displays the master table data fields in their native order (the order in which they appear in the database), with the addition of nested sublists denoting relationships with related tables.

You can select data fields for export in the following ways:

- Drag a single field name from Select the Fields on the left to Export Field List on the right.
- Click a single field name from Select the Fields while holding down the Shift key.
- Select a single field name from Select the Fields and click the single arrow.
- Click on the double arrow to move all fields to the Export Field List.



Using the single arrow or shift-clicking on a field will add fields in the order they were selected. You can also drag a field from left to right, and it will be placed above the field it is dropped on. You can change the order of the fields in the list on the right by dragging them to a new position.

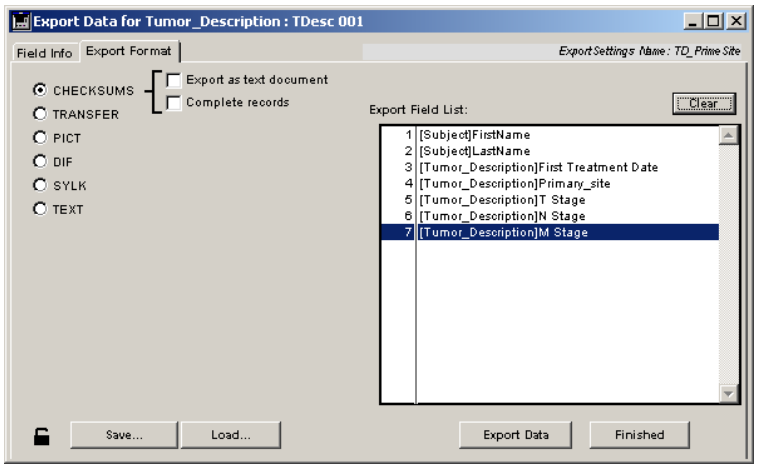
When the list fills the screen, you can add a new field name to the end of the list (no matter where you drop it) by dragging while holding down the Shift key.

To remove fields from the Export Field List, do one of the following:

- Drag a single field to the Trash in the lower right of the form.
- Click on a single field in the Export Field List while holding down the Shift key.
- Click Clear in the upper right to remove all fields in the list.

Selecting format for export

Otobase can export data files in a number of different formats depending on how the data will be used. In the Export Data Form, select the Export Format tab.

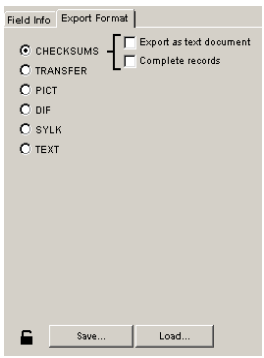


Depending on the format you choose, different options will appear. The first two formats are CHECKSUM and TRANSFER, which are used for sharing data with other participants in a study using Otobase. The last three formats, DIF, SYLK, and TEXT, are all text formats, which can be imported by spreadsheets and statistical packages as well as other databases. We will examine only the first two options. For an explanation of all export functions, see Chapter 5 in the Otobase User Guide, "Exporting and Reporting."

Exporting the CHECKSUM format

The CHECKSUM export type is unique to Otobase and is primarily used to report interim data in a clinical trial. Exporting CHECKSUM files allows both the sender and recipient to be sure that the data has not been tampered with or changed without having to share the actual data. For more information on how checksums work, see Chapter 9 in the Otobase User Guide, "Database Design and Theory."

When exporting checksums, you have two options:



- Export as text document
- Complete records

If you choose Export as text document, Otobase generates a tab-delimited text document that includes the checksum information. This text document can be opened by any word processing or spreadsheet program.

If you do not choose to Export as text document, Otobase generates the checksum in a TRANSFER document, which can only be

interpreted by Otobase. Although both CHECKSUM formats include the same information, the text file format can be tampered with. To ensure a higher level of security for your checksum data, do not check "Export as text document."

When you export the checksum as a TRANSFER document, the recipient can open the document in Otobase, extract the checksum information, and place this information in a text document for analysis. The recipient can also compare the checksum information with data records they have already imported in the past to check for changes. For more information, see "Importing a TRANSFER document" on page 14.

Selecting the "Complete records" option sends the checksum stored internally for the entire record in the database, rather than calculating checksums for the individual fields selected for export. If you are participating in a clinical trial, selecting this option allows you to send secure information about your files without sending all the data in the files.

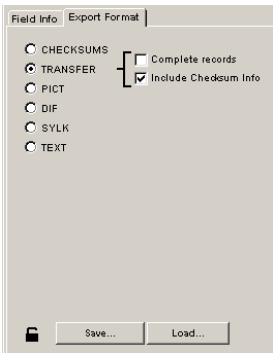
"Complete" records
Since TRANSFER documents may include data from more than one table, the field list is evaluated for the tables exporting complete records. Because of this, to use the Complete records option you must specify at least one field from each table used in the export.

Exporting the TRANSFER format

The TRANSFER format is unique and can only be interpreted by Otobase. When exporting TRANSFER documents, you have two options:

- Complete records
- Include Checksum info.

If you check Complete records, Otobase exports all fields in a record and ignores the export field list with one exception (see "Complete records require one field" above).



Include Checksum Info is selected by default. This option offers a number of advantages for the person importing these files in a clinical study. First, since the checksum information can be placed in a text file, the person importing the data can check to see what is in the TRANSFER document, prior to importing the records. Second, the person importing the checksum for an imported record can compare it to the checksum from any pre-existing records. In this way, the data for import can be checked prior to updating or replacing records and previous secure data will not be lost. Additional import options are available based on this checksum analysis (see "Importing a TRANSFER document" on page 14).

Saving exports

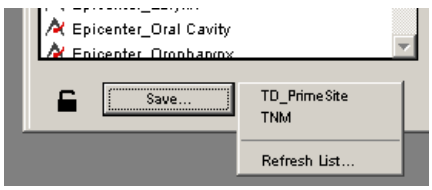
Often you may need to export the same group of fields on more than one occasion. The Saved Export feature allows you to save the settings for common exports.

Export settings can be saved in as database records, or they can be saved to disk to allow sharing with other Otobase users, specifically ones who may be participating in the same study. Saving an Export will store both the specified export fields and format.

To save an export to a database record

1. Complete the Export Data form by choosing fields and selecting a format.
2. Click Save.
   A Request dialog appears.
3. Enter a unique name for this export and click OK. If you use the name of an existing Saved Export you will be asked if you want to replace the older version of that Saved Export.

To load an export from a database record



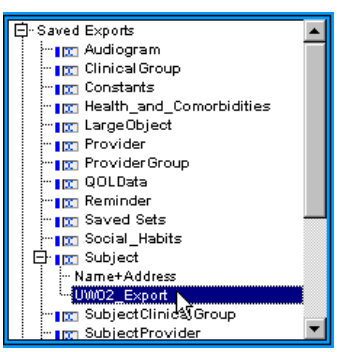
1. On the Export Settings form, click Load.
   A pop-up list of available Saved Exports for that master table appears.
2. Select the appropriate Saved Export.

Note: Use the Refresh List selection if you believe there is a Saved Export available, but it does not appear in your pop-up list. This is rarely necessary in a client-server environment.

Saving and loading Saved Exports outside Otobase

Administrators and subadministrators can save the export settings used to create Saved Exports to a file on their computer and then reload them. This is useful when exchanging data in multi-site trials. By using this function, you can avoid having to rebuild the exports that are used to create Saved Exports.

To save a Saved Export to disk

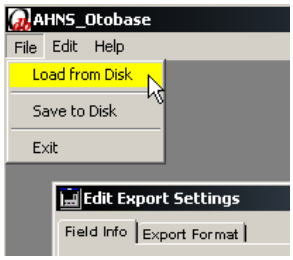


1. Open the Preferences form (File > Preferences).
2. Click Export/Grouped Export.
3. Open the Saved Exports list in the box on the right by using the plus sign (Windows) or arrow (Mac).
4. Find the Saved Export you wish to save to a file on your computer by opening the tables that have plus signs or arrows next to them.
5. When you have found the Saved Export, double-click it to open the Edit Export Settings form.
6. Click File > Save to Disk.

7. In the Save As dialog, browse to a destination folder, name the file, and click Save.
   The export settings used to create the Saved Export will be saved in a special format that allows them to be reloaded into Otobase.

To load a Saved Export from disk

1. Open the Preferences form (File > Preferences).
2. Click Export/Grouped Export.
3. Open the Saved Exports list in the box on the right by using the plus sign (Windows) or arrow (Mac).
4. Find the table that matches the one used to create the Saved Export you are loading, then do one of the following:
   - With the table name highlighted, click New Saved Export to open a blank Edit Export Settings form.
   - Double-click on a Saved Export name within the table to open an existing Edit Export Settings form.



5. Click File > Load from Disk.
6. In the Open dialog, browse to the file that contains the Saved Export you wish to load, and click Open.
   The Edit Export Settings form will change to reflect the settings from the file you loaded.
7. Click Save.
   A Request dialog appears.
8. Enter a unique name for this export and click OK. If you use the name of an existing Saved Export, you will be asked if you want to replace the older version of that Saved Export.

Special note on Windows vs. Mac

If you are trying to share files between platforms (for example, Windows to Mac), the normal Open dialog may not show the file you are looking for. This affects several menu items:

- File > Load from Disk
- Import/Export > Import TRANSFER Doc
- Import/Export > Encrypt TRANSFER Doc
- Import/Export > Decrypt TRANSFER Doc
- Import/Export > Decrypt a Grouped Export
- Clinical Group > Import Study Tools

In this case, hold down the Shift key while selecting the menu item. This forces the Open dialog to display all files.

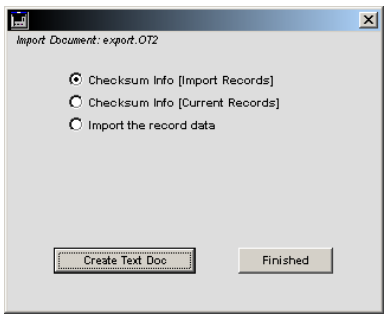
Importing a TRANSFER document

This menu item allows you to open, examine and import TRANSFER-type export documents that contain data records and/or checksum data. Selecting this item will open the standard dialog to let you choose a file to import.

After you choose the file, the Import TRANSFER Doc dialog appears, giving you three options:

- Checksum Info import records
- Checksum Info current records
- Import the record data.

Here is a look at how the three options work:



Checksum Info Import Records

This option allows you to simply examine the TRANSFER document to see what information it contains before taking steps to import it. Selecting this option then clicking the Create Text Doc button will generate a tab-delimited text file that will include the required internal ID fields for each record that has been exported, along with the checksum for the exported data fields. If data fields were exported without checksum calculations, the text file will so indicate. Here is an example of the text file this option generates:

```
Record Export Checksum Info
Export date: 04/25/1999:

Tablename                   Exported Field Numbers
Tumor_Description           1,5,9,16,17,18,

Tablename                   ID Field #1       ID Field #2
Tumor_Description           Subject_ID        Tumor_No

Tablename                   ID Field #1       ID Field #2       Checksum for exported fields
Tumor_Description           251000            174000            81827828
Tumor_Description           275000            215000            1520154295
Tumor_Description           277000            218000            584311072
Tumor_Description           38000             224000            1094207930
```

The file includes:

- File type identification and date of export.
- The table(s) included in the export and their exported field numbers. In this example, only Tumor_Description fields were included in the export since we were only exporting records from the Tumor Description table. Six fields were included in the exported data and the checksum calculations: 1 (Subject_ID), 5 (Tumor_No), 9 (Primary_site),

16 (T Stage), 17 (N Stage), and 18 (M Stage). These are the four fields specified on the Export Settings form plus the two required ID fields for the Tumor_Description table.

Note: The ID fields could have been explicitly included in the Export Settings. Since they were not, the required ID fields were automatically added.

- Names of the required ID fields for the included table(s).

Checksum Info Current Records

This option allows you to compare the exported records to the records that they would replace if you imported them. Selecting this option then clicking the Create Text Doc button will create a tab-delimited text file containing the required internal ID fields for each record exported. The text file will also show the calculated checksum for any existing records with the same internal IDs currently residing in the destination data file that would be updated if the "new" record data were imported. In addition, if the checksum data was included in the TRANSFER-type document, Otobase will compare the existing destination data file record fields and the data fields that would be imported from the TRANSFER-type file. Here is an example of the text file this option generates:

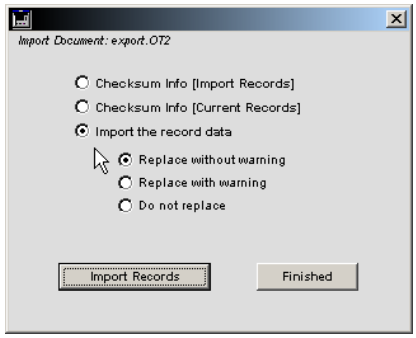
```
Record Export Checksum Info
Export date: 08/25/1999:

Tablename               Exported Field Numbers
Tumor_Description       1,5,9,16,17,18,

Tablename               ID Field #1     ID Field #2
Tumor_Description       Subject_ID      Tumor_No
Previous record status: 0=none, 1=found w/ same checksum, 2=found w/ different checksum, 3=more
than one record found

Tablename               ID Field #1     ID Field #2     Checksum for        Previous record
                                                        exported fields     status
Tumor_Description       251000          174000          81827828            1
Tumor_Description       275000          215000          1520154295          1
Tumor_Description       277000          218000          584311072           2
Tumor_Description       38000           224000          1094207930          0
```

You can use the information in the "Previous record status" column to verify any changes in previously shared data. Note the number "2" in the second to last record; this indicates that the checksums did not match and something has changed.

Import the record data

Selecting this option gives you three more choices before you import data. Otobase uses the required internal ID fields that are always included in the TRANSFER type document to search for an existing record in the data file. The three options differ in how they affect existing records:

- **Replace without warning:** This will update the data fields in existing records with the imported data without warning the user.
- **Replace with warning:** This will warn the user before each update is performed. The user can choose to skip that record or update it accordingly. The displayed confirmation dialog will include the required internal ID fields for that record.
- **Do not replace:** This will leave any existing records untouched.



If no existing record is found, Otobase creates a new one and populates it with the imported data fields.

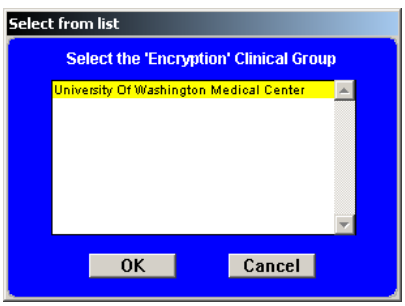
Note: If the TRANSFER type document does not include the actual record data, the Import the record data option will be disabled.

Encrypting a TRANSFER document

To ensure the security of clinical data being shared by disk, e-mail or networked computers, as well as for verification purposes, Otobase allows you to encrypt TRANSFER documents. Otobase will manually encrypt a TRANSFER document when you select this menu item. For this function to work, the Clinical Group you are encrypting the document for must be designated as a study (see "Designating the group as a study" on page 22).

To encrypt a TRANSFER document

1. From the Administrator Menu Bar, click Import/Export > Encrypt TRANSFER Doc.
   An Open dialog appears.
2. Select the TRANSFER document you want to encrypt.
3. A Select From List dialog appears with the names of Clinical Groups that have been designated as studies and have private (encryption) keys.
4. Click the appropriate group name on the list, and click OK.
   The encrypted document will replace the unencrypted copy.



Decrypting a TRANSFER document

An encrypted TRANSFER document can be manually decrypted using this item. First, a standard dialog will be presented to let you select the TRANSFER document to be decrypted.

The encrypted TRANSFER document includes information that is used to select the proper decryption key. The decryption key to be used is identified by:

- The Clinical Group's List Name, which should be the same for all the participants in a multi-site trial.
- The study participant's ID.

The decrypted document will replace the encrypted copy.

Part 3

Setting up a trial using automated features

Otobase uses such automated features as Grouped Exports and Export/Import Study Tools to streamline the process of setting up trials. Part 1 of this manual explained some of the concepts behind setting up a trial; this section offers step-by-step instructions for both the study coordinator and participant.

First, we'll look at the steps that a study coordinator goes through to set up the Clinical Group record, encryption, searches, exports and other tools for running a trial, and then we'll examine the steps for study participants starting on Page 34. For visual overviews of the steps, see "Steps in setting up a clinical trial: Study coordinator" on page 19 and "Steps in setting up a clinical trial: Participants" on page 34.

Steps for the study coordinator

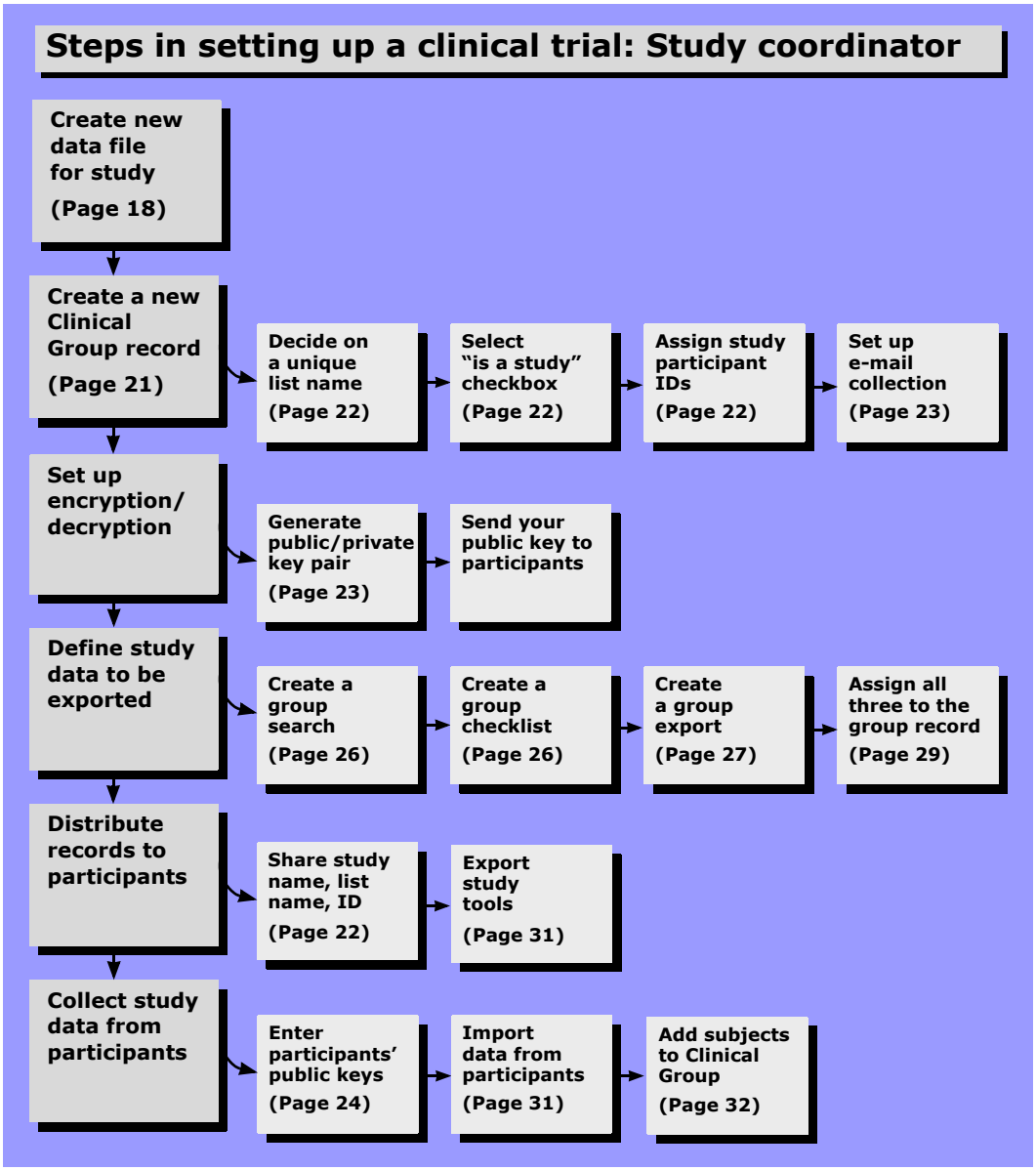
The study coordinator will use his or her copy of Otobase to set up the Clinical Group record for the trial and then share this information with participants. The coordinator also builds the study search, checklist and export definitions and then shares these with participants using the Export Study Tools function. Once encryption and decryption have been set up, sharing of data can begin, with participants sending their encrypted exports to the coordinator, who maintains all records associated with the study (or at least the checksum information for the records).

We will begin the section describing how the coordinator can make sure that data being collected for the study remains separate from his or her own subject data in Otobase.

Keeping study data separate

To ensure the integrity of the data being shared in a multi-site clinical trial, it is recommended that the study coordinator create a new clinical trial data file to use with his or her original version of Otobase.

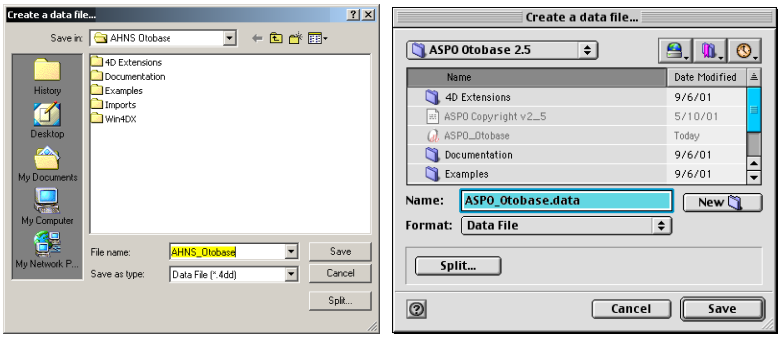
Keeping the data separate will simplify long-term management of a study, especially if the study coordinator is running multiple studies at the same time. A separate data file also ensures that records not involved with the study will not be accidentally affected by data import.



To create a new data file

1. Double-click the Otobase icon on your computer.
   The Password dialog appears.
2. Log in as the administrator.
3. Enter the administrator password for the data file you were last using.
4. While holding down the Alt key (Windows) or Option key (Mac), click Connection.
   Otobase opens and the Open data file dialog appears.

5. Select New…
   The Create a data file… dialog appears.



Create file dialogs: Windows (right), and Macintosh

6. Browse to a location where you wish to save the new file.
7. In the Name field, type in a unique name for the new data file.
8. Click Save.
   You will be prompted that there are no passwords assigned to the new data file, and asked about synchronizing the data and structure files.
9. Click Yes.
10. Follow the dialogs asking you to enter and confirm a new password.
11. Enter a new Participant ID number between 0 and 999, and click OK.

Note: You can always reconnect to previously created data files by holding down the Alt key (Windows) or Option key (Mac) and browsing to a different data file.

Be careful when switching between data files

Although it's a good idea to use a separate data file for the study, managing more than one data file can be tricky. Here are two cautions:

First, be sure when switching between data files that you are using the correct file to enter study data or nonstudy data. To check which data file you are using, click Help > About Otobase (Windows) or Apple > About Otobase (Mac) and select the Folder Info tab.

Second, if you use different passwords for the various data files, keep a record of them. Otobase remembers the last data file it was connected with and will require you to use the password associated with that file to initially log in. When you switch to a different data file, you'll have to enter a password for that file after Otobase synchronizes the data and structure files.

If you are ever at a total loss to recall which data file you were last connected with and cannot log in because you are using the incorrect password, follow these steps:

1. Uninstall Otobase (this will not affect your data files).
2. Reinstall the program.
3. Use the initial Administrator/Otolith2 login and password combination.
4. Browse to whatever data file you wish to work with and click Open to connect with it.
5. Following synchronization of the structure file and data file, log in with the password stored in that data file (or create a new password at this time).

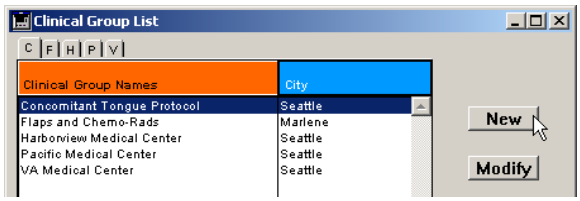
Setting up the Clinical Group record

This section will first show you how to create a new Clinical Group record, and will then explain how to fill out the record in preparation for a trial and set up encryption/decryption keys. The finished Clinical Group record will also have the study group's search, checklist and export definitions. These will be explained starting on page Page 26.

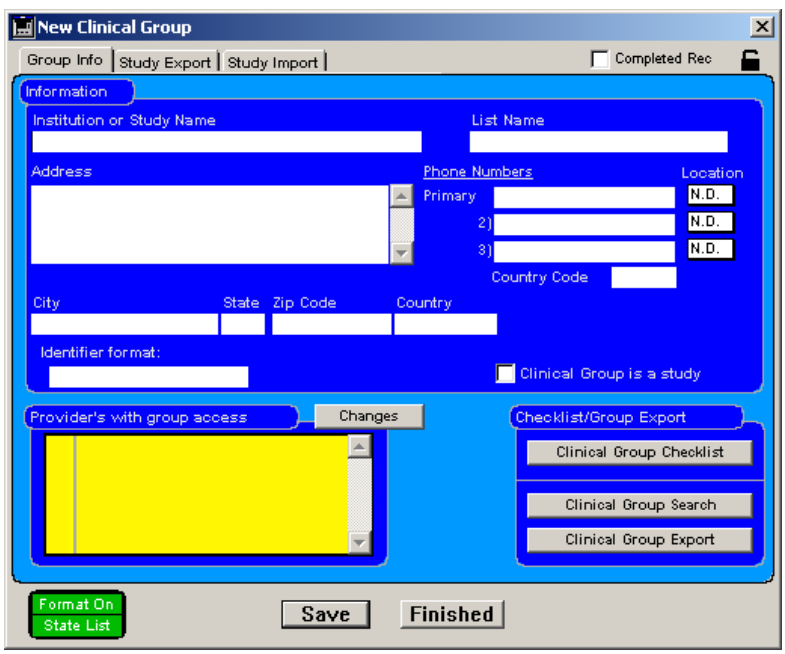
Note: Only users logged on as administrator or subadministrator can create a new Clinical Group record. For an explanation of the different user classes in Otobase, please refer to Chapter 1, "Getting Started," in the Otobase User Guide.

To create a new Clinical Group record

1. With the Home Window or Subject List open, Select File > Clinical Group Info.
   The Clinical Group List form appears, with a list of all Clinical Groups and buttons to add, modify or delete groups.
   Group administrators will be presented with the list of Clinical Groups they administrate.



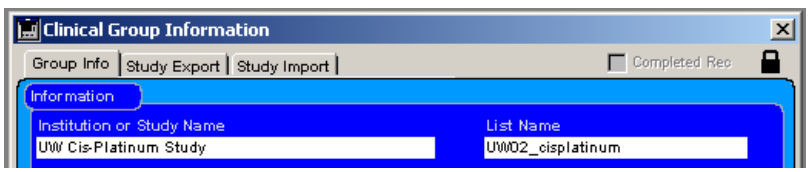
2. Click New.
   A New Clinical Group form appears. You can open an existing Clinical Group Information form by double-clicking on a group name in the list, or selecting the name and clicking Modify.



The Clinical Group form has three tabs, Group Info, Study Export and Study Import. The administrator and subadministrators can view, copy and change all of the fields on the second and third tabs of the form. Group administrators cannot access any of this information.

Choosing a unique list name

The Clinical Group form has two boxes for naming the group: Institution or Study Name, and List Name. We recommend that you choose a List Name that contains numerals or symbols and cannot be confused with the name of another institution or group. Study participants will need to use this same List Name in the data files they are using for this particular study, so the coordinator must ensure the name doesn't conflict with names that participants may already be using. It is also a good idea for the study coordinator to use part of the List Name as part of the name of searches, exports and checklists that are associated with the study to make sure these don't conflict with other such items in participants' data files. We recommend that a prefix be used as part of all records associated with the trial, for example UW02_GroupSearch, UW02_GroupExport, etc.



Designating the group as a study

Selecting the "Clinical Group is a study" checkbox on the Clinical Group Information form allows Otobase to substitute Study Participant IDs when it encrypts data for export, and is also important in automating the encryption process.

In addition, selecting this checkbox makes it easier to search for all subjects in clinical studies.

Assigning Study Participant IDs

The Study Participant ID ensures that each site taking part in a study is uniquely identified. This enables Otobase's encryption/decryption feature to work properly. The coordinator should assign a unique number to each participant, including him or herself. We recommend the coordinator take the number 0 and begin with the number 1 for assigning IDs to participants.

Note: All participants in a study must select the "Clinical Group is a study" checkbox on the Clinical Group form to allow the substitution of Study Participant IDs in exported data, as well as the automation of the encryption process.

To assign a Study Participant ID for exported data

1. Log onto Otobase as Administrator.
1. On the Clinical Group form, click the Study Export tab.

2. Make sure the form is unlocked by clicking on the black, closed lock icon.
3. Enter a number between 0-999.
4. Click OK to save the change.

Sharing the group record

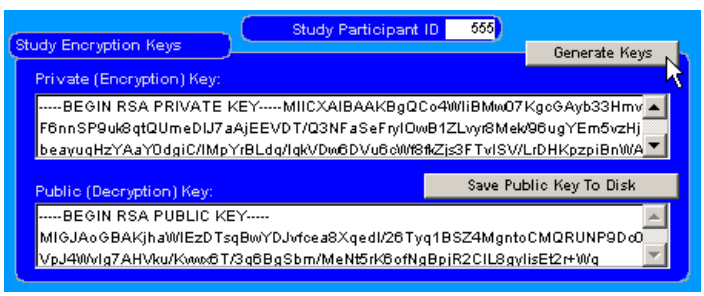
Once the coordinator has set up a clinical group record, he or she needs to share its data so participants can set up matching records. The minimum information participants will need is the study name, the unique list name and their Study Participant ID, plus the exported study tools (see “Exporting study tools” on page 31). If the study will use e-mail communication, the coordinator’s e-mail information should also be included.

Setting up encryption

The process of encryption/decryption of data begins on the Clinical Group form. Follow these steps to generate a public/private key pair.

To generate public/private key pairs

1. On the second tab of the Clinical Group form (Study Export), make sure you have entered a Study Participant ID.
   The Generate Keys button is enabled.
2. Click Generate Keys.
   Otobase creates a public/private 1024-bit encryption key pair.



3. Do one of the following:
   - Click Save Public Key to Disk to generate a text file that you can use to share the public key with whoever will be importing your data.
   - Highlight the public key, copy it, and then paste it into an e-mail message or other word processing program for sharing.
4. Click OK to save the keys in the Clinical Group form.
   If you try to modify previously created keys you will be warned before saving the record since an inadvertent change will destroy the utility of the paired keys.

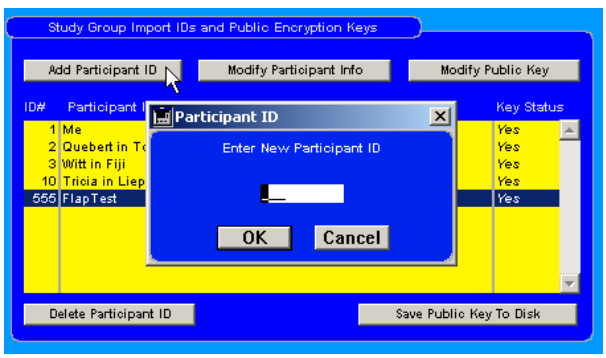
Setting up decryption

The third tab of the Clinical Group form allows you to set up decryption of shared data. On this tab:

- The study coordinator can enter the names and Study Participant IDs of all those involved in the study, as well as enter or modify participants' public keys to allow decryption of their data.
- Participants can enter the coordinator's public key to enable them to decrypt study tools or other data sent from the central collection site.

Study participants should generate their own key pair and send the public (decryption) key to the study coordinator. The coordinator can then import the participant's public key using the following procedure.

To add Study Participant IDs and public decryption keys



1. On the third tab of the Clinical Group form, click Add Participant to begin the process of entering the participant's name, ID number and public key.
   A dialog appears for entering the participant's ID.
2. Enter the ID and click OK.
3. Click Modify Participant Info.
4. Enter a name in the dialog and click OK.
5. Click Modify Public Key.
   A dialog will ask you to confirm that you want to modify the public key for this participant.
6. Click OK.
7. Copy the public key that this participant has sent to you, paste it into the Public Key dialog, and click OK
   The Key Status column at right will show the italicized word "Yes" to indicate that you have stored the participants's key.

Clicking Save Public Key to Disk allows you to create a text file with the selected participant's public key. The file can then be distributed on disk or opened in a word processing program for copying and pasting. You can also remove a participant from the list by clicking Delete Participant ID.

Ideas for using Otobase's encryption tools

Verifying data using encryption keys (without sending the data)

Otobase's checksum feature gives you a powerful tool for verifying unshared data (see Page 7). The checksum information can be shared by itself in a text document form or sent as a TRANSFER document.

If the checksum information is sent as a TRANSFER document it can be encrypted and decrypted just like a TRANSFER document with data. The encryption/decryption process means that the same level of verifiability pertains to the checksum information by itself.

Backing up data at a central location using encryption keys

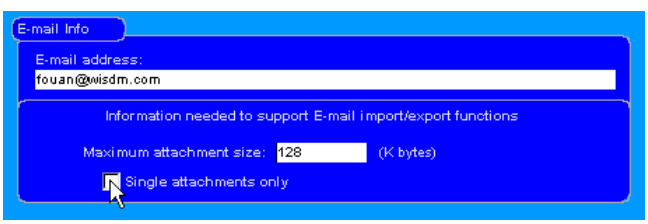
If participants choose to maintain their independence by sending only checksums until the end of a study, it is crucial that each site can guarantee that their complete data sets will be protected from loss since they have the only copies. As a safeguard, the study coordinator can ask participants to encrypt complete records with a public/private key combination that is not being shared with the coordinator.

To accomplish this the participant should set up an additional "shadow" Clinical Group record that will include the same Sequential Search and Study Participant ID as the original study group. The group export can be the same or can include other fields or complete records. These encrypted records can then be sent to a central storage location as an additional source of data backup. If the original records are ever lost, the encrypted backup copies can be sent to the originator, who can decode them and reload them in his or her database. Alternatively, the decryption key can be given at that time to the study coordinator along with the records (see below). To further guard against the possible loss of access to the encrypted data due to misplacement of the unshared public (decryption) key, the originator can arrange to send the public key to a trusted third party who will not release it without the originator's consent.

The choice of which Study Participant ID to use depends on who the intended recipient of the backup records will be. If the originator will be re-importing the backup copies, the Study Participant ID should be left blank. If the study coordinator will be receiving the backup records, the ID should be the one assigned in the original study. In this case, the study coordinator will set up a new Clinical Group record for the "shadow" Clinical Group with the same List Name used by the participant. The backup decryption key is entered on this form.

Setting up study e-mail

The second page of the Clinical Group form allows you to enter the e-mail address of a central data collection site for the study. If participants choose to export data automatically via e-mail enclosures, it will be sent to this address.



Maximum attachment size

Some e-mail systems limit the size of e-mail enclosures (attached documents). The default value is 128 Kb. If an export document exceeds the specified size the document will be split into multiple enclosures and reassembled when it is imported.

Single attachments only checkbox

Some e-mail systems limit the number of e-mail enclosures (attached documents) per e-mail. Selecting this option causes export document(s) to be sent out as a series of separate e-mails. This is rarely needed and increases the time needed for the export. Do not choose this option unless you are certain that you need to.

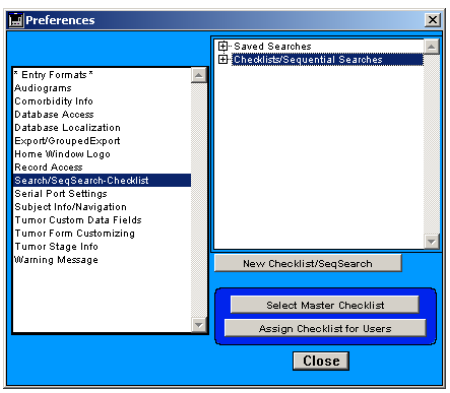
Creating a Clinical Group Search and Checklist

If you've already created the group's Checklist, Search and Export, skip to the sections about assigning them to the Clinical Group record on Page 30.

The Clinical Group Search and Clinical Group Checklist are both Sequential Searches, built from individual Saved Searches. Otobase executes multiple Saved Searches for a table separately, and then combines the resulting sets using the "AND" operator. A Checklist, instead of searching for all records meeting certain criteria, ensures that a new record being saved in Otobase meets the criteria to begin with.

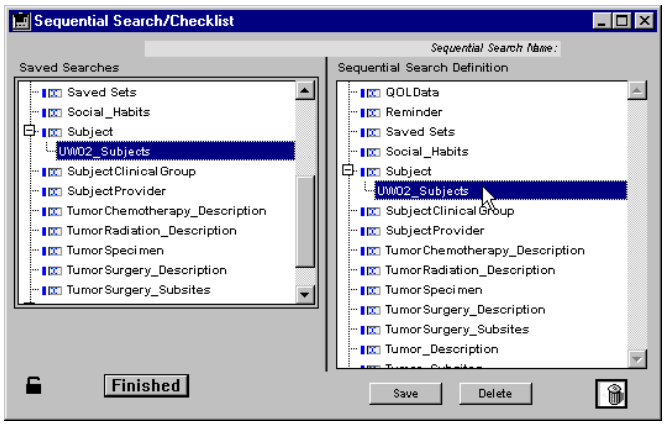
This section will explain how to build a Sequential Search. Because the process of building a Checklist is essentially the same, it will not be explained separately (although the Checklist must be assigned to an individual Provider record for it to work). For more information, see Chapter 2, "Providers and Clinical Groups," Chapter 4, "Searching," and Chapter 6, "Preferences," in the Otobase User Guide.

To create a Sequential Search



1. Open the Preferences form by clicking File > Preferences from the Home Window or Subject List menu bars.
2. Click Search/SeqSearch-Checklist in the list on the left side of the form.
3. Select Checklist/Sequential Searches from the list on the right, and click New Checklist/SeqSearch.
   The Sequential Search/Checklist creation form appears, with a list of any Saved Searches in the database (organized by table). An item with a plus sign (Windows) or arrow (Mac) contains a sublist of Saved Searches.

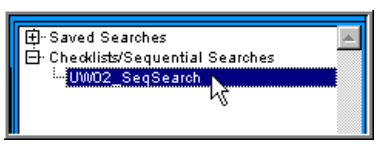
4. From the Saved Searches list on the left, use the plus signs or arrows to open list items and find the Saved Search(es) that you created.



5. Drag the Saved Searches you wish to assemble into a Sequential Search to the list on the right.
   You can change the order of the Saved Searches by dragging them to a different position in the sublist.
6. When you have built your Sequential Search, click Save.
7. Using the dialog, name the search, then click OK.

   Note: It is important to name Sequential Searches, Checklists and any individual Saved Searches in a unique manner to avoid conflicts when sharing them with participants in the trial. We suggest using a prefix such as UW02_.

8. Click Finished.
   The newly created Sequential Search or Checklist search appears in the list on the Preferences form.



The administrator or subadministrators can modify Sequential Searches and Checklists from the Sequential Search/Checklist form by adding new Saved Searches or dragging old ones to the Trash.

To delete a Sequential Search or Checklist, open the form and select Delete.

Creating a Clinical Group Export

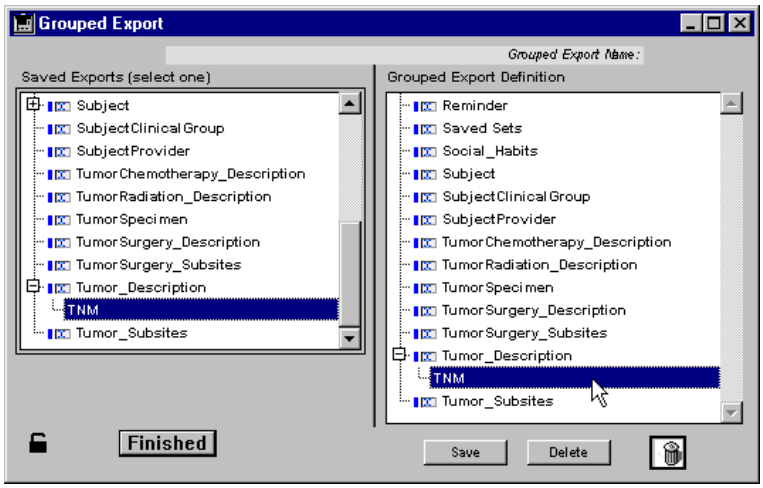
After defining the searches that allow participants to save and find data of interest to the study, you can use the same searches to define the data that will be exported from each site's version of Otobase. Exporting data involves selecting an export format and defining the fields to be exported from each table. For an explanation of setting up an individual export, see "Sharing data manually using special formats" on page 8, as well as Chapter 5, "Exporting and Reporting," in the Otobase User Guide.

The export you will assign to all participants in the study is a special Otobase function known as a Grouped Export. It combines Saved Exports from multiple tables within the database and allows study participants to export all data relevant to the study with just a few clicks (see "Exporting a Grouped Export" on page 36).

The following procedure explains how to set up a Grouped Export.

To create a Grouped Export

1. Click the Export/Grouped Exports list item on the Preferences form.
2. Select Grouped Exports from the list on the right, and click New Grouped Export. The Grouped Export form displays.



3. From the Saved Export list on the left, use the plus signs or arrows to open list items containing Saved Exports.
4. Drag the Saved Exports you wish to assemble into a Grouped Export to the list of tables on the right.
   Otobase will only allow you to drag a Saved Export to the table it was created from, and you can only drag one Saved Export per table. If a Saved Export includes fields from related tables, these fields are ignored in executing a Grouped Export.
5. When you have built your Grouped Export, click Save.
6. Using the dialog, name your Grouped Export, then click OK

   Note: It is important to give Saved Exports and Grouped Exports unique names so they don't conflict with other such exports already being used by participants in the trial. We suggest using a prefix such as UW02_.

7. Click Finished.
   The name of the new Grouped Export appears in the sublist on the Preferences form.

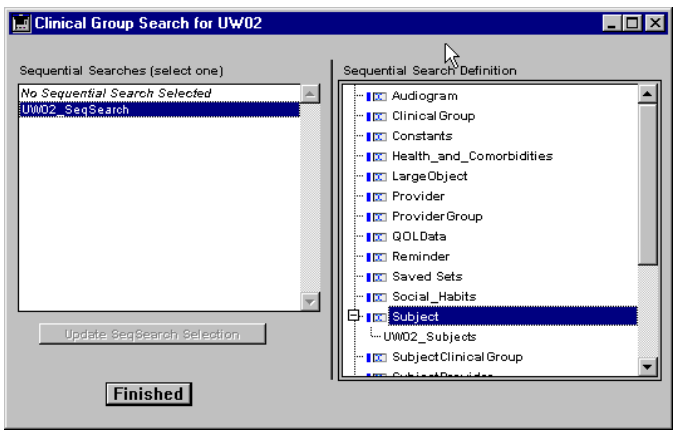
The administrator or subadministrators can modify previously saved Grouped Exports from the Grouped Export form by adding new Saved Exports or dragging old ones to the Trash. To delete a Grouped Export, open the form and select Delete.

Assigning a Clinical Group Search and Export

Once the study coordinator has defined the Clinical Group Search and Export, he or she can assign them to the Clinical Group record. We will explain the procedure for assigning a Search; the steps for assigning an export to the group are nearly identical.

To assign a Clinical Group Search

1. Create a Sequential Search for the group (see "Creating a Clinical Group Search and Checklist" on page 26).
2. On the Clinical Group Information form, click Clinical Group Search.
   A form appears with the name of the Clinical Group at the top, and a list of the Sequential Searches stored in the database.



3. In the left-hand list, click on the Sequential Search you wish to assign to the Clinical Group.
   You can view the Saved Searches used to define the Sequential Search in the right-hand list by using the arrows or plus signs to open tables that contain the searches.

   Note: To review the contents of an individual search, double-click on the name of the search, in this example "UW02_Subjects." The search will open. You cannot edit the search here, just review it.

4. Click Update SeqSearch Selection.
   The text on the Clinical Group Search button changes to italics to signal that a search has been assigned.

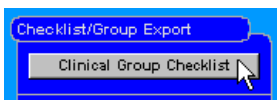
You assign Grouped Exports to Clinical Groups using the same procedure, starting with the Clinical Group Export buttons on the form. These are used for selecting complete or partial datasets for export to a coordinating institution in a multi-center clinical study.

Assigning Checklists

Once you have created a checklist, you must assign it to a Clinical Group, and then to Providers, to make it properly test for your criteria.

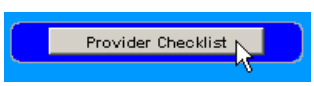
To assign a Checklist to a Clinical Group and Providers

1. Select File > Clinical Group Info to open the Clinical Group List, then double-click on the group you wish to assign the checklist to.
   The Clinical Group form opens.
2. Unlock the Clinical Group form by clicking on the black lock.
3. Click Clinical Group Checklist.
   A form opens with a list on the left of all Checklists saved in the database.



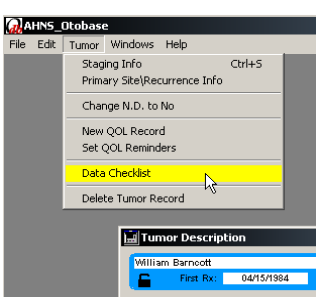
4. Click the Checklist you would like to associate with this Clinical Group.
   The Checklist Definition box displays all tables, with sublists attached to the tables that contain the Saved Searches comprising your checklist. You can double-click a Saved Search to display it and check the criteria.
5. Click Update Checklist Selection.
   The Clinical Group form appears again. The text on the Clinical Group Checklist button has changed to italics to signal that a Checklist is associated with this Clinical Group.

6. Open a Provider Information form by selecting the File > Provider Info menu item and double-clicking on a provider name.
7. Unlock the Provider form and click Provider Checklist.
   The form that appears allows you to select a Checklist and decide whether to let the user to override it.
   Whenever the user saves a record, Otobase will run the Saved Searches used to create this Checklist to enforce the criteria you set.



Using an assigned Checklist

You can pre-test a Checklist before saving a new or modified record or test it on a previously saved record by selecting the Data Checklist menu item found in one of the menus attached to the data entry form (for example, Subject > Data Checklist or Tumor > Data Checklist).



A Checklist pretest can always be dismissed by selecting the Close button. The administrator or a subadministrator has the option to enforce a Checklist when the record is saved (Recheck is the only option) or allow a user to save the record anyway (Accept is also an option).

Exporting study tools

The study coordinator can export the Clinical Group Checklist, Search and Export using a single menu item. Otobase creates a special TRANSFER-type document with a file extension of OT3, which bundles all three items into one file and encrypts them using the coordinator's private key if data encryption has been set up for the trial. Participants who have received the public key from the coordinator and entered it on the third tab of the Clinical Group form may then import the Checklist, Search and Export definitions into their version of the database using the Import Study Tools item (see "Importing study tools" on page 35). The imported definitions will be automatically attached to the Clinical Group record.

To export the bundled Clinical Group Checklist, Search and Export

1. Make sure you have created all three items; the buttons on your Clinical Group record for this study should all be italicized. Also make sure you have saved the Clinical Group record.
2. On the Clinical Group menu bar, click Clinical Group > Export Study Tools.
   A Save As dialog appears, allowing you to browse to a location on your computer to save the OT3 file.
3. Choose a name for the file, and click Save.
   The file is now ready for sharing with trial participants.

To see the procedure study participants will follow to bring the study tools package into their version of Otobase, see "Importing study tools" on page 35.

Importing study data

After all participants create matching Clinical Group records and send the study coordinator their public keys, sharing of data can begin. We will explain the process of importing and decrypting Grouped Exports, since this is the automated method of sharing study data. For an explanation of importing and decrypting TRANSFER documents manually, see "Importing a TRANSFER document" on page 14 and "Decrypting a TRANSFER document" on page 17.

Importing a Grouped Export

Selecting this item from the Administrator Menu Bar will open a dialog that asks you to choose an import method, either Disk File, Disk File from e-mail, or e-mail. Depending on your choice, you will either browse to a folder containing the Grouped Export documents, or be asked to enter your password for your Otobase e-mail connection.

If you choose a Grouped Export document and all of the associated disk documents are in the same folder together, the Import Grouped Export form displays (see "Importing a TRANSFER doc-

ument" on page 14 for information concerning the different options on the form, and a note about opening files saved in a different operating system).

If you select either of the two Checksum Info options on the Import GroupedExport form, a tab delimited text document will be generated for each of the Grouped Export TRANSFER documents and placed in the same folder with the Grouped Export's TRANSFER documents.

Note: Each document making up a Grouped Export can be treated as an independent TRANSFER document and imported manually. For the automated import function to work properly, however, all of the documents in the Grouped Export must be together in the same folder.

Decrypting a Grouped Export

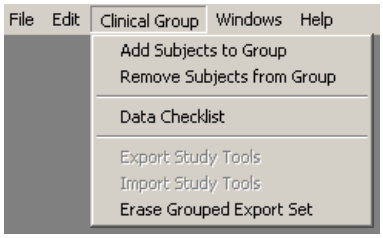
This menu item allows you to manually decrypt a Grouped Export document set. Manual decryption is necessary for Grouped Exports saved to disk, whereas e-mailed documents are automatically decrypted after downloading and conversion. Choosing the Decrypt a Grouped Export menu item will open a standard dialog allowing you to select one of the TRANSFER documents to be decrypted. This feature automatically verifies that all of the required documents are together before proceeding with decryption.

The decrypted documents will replace the encrypted copies.

Assigning subject records to the Clinical Group

After importing study data from participants that includes new subjects, the study coordinator needs to assign all imported subject records to the Clinical Group record created for the study to make sure they are uniquely identified within his or her data file. You can do this using a menu item attached to the Clinical Group record.

To add subjects to a Clinical Group



1. Open the Clinical Group record for the study by double-clicking on the name in the Clinical Group List.
2. From the menu bar, select Clinical Group > Add Subjects to Group.
   A Search for Subjects form opens.
3. Search for the set of subjects you wish to add and drag it to the Drop Selected Subject Set box on the form.
   All subjects in the set will be assigned to the Clinical Group.

Note: One way to search for the newly imported subject records is to create a set of all Clinical Groups and drag it to the Subjects table list, and then create a set of all subjects. By combining these two sets using the Difference function, you will have located all subjects not yet assigned to a Clinical Group. For more information on how to create searches and combine sets, see Chapter 4, "Searching," in the Otobase User Guide.

To remove a group of subjects from a Clinical Group

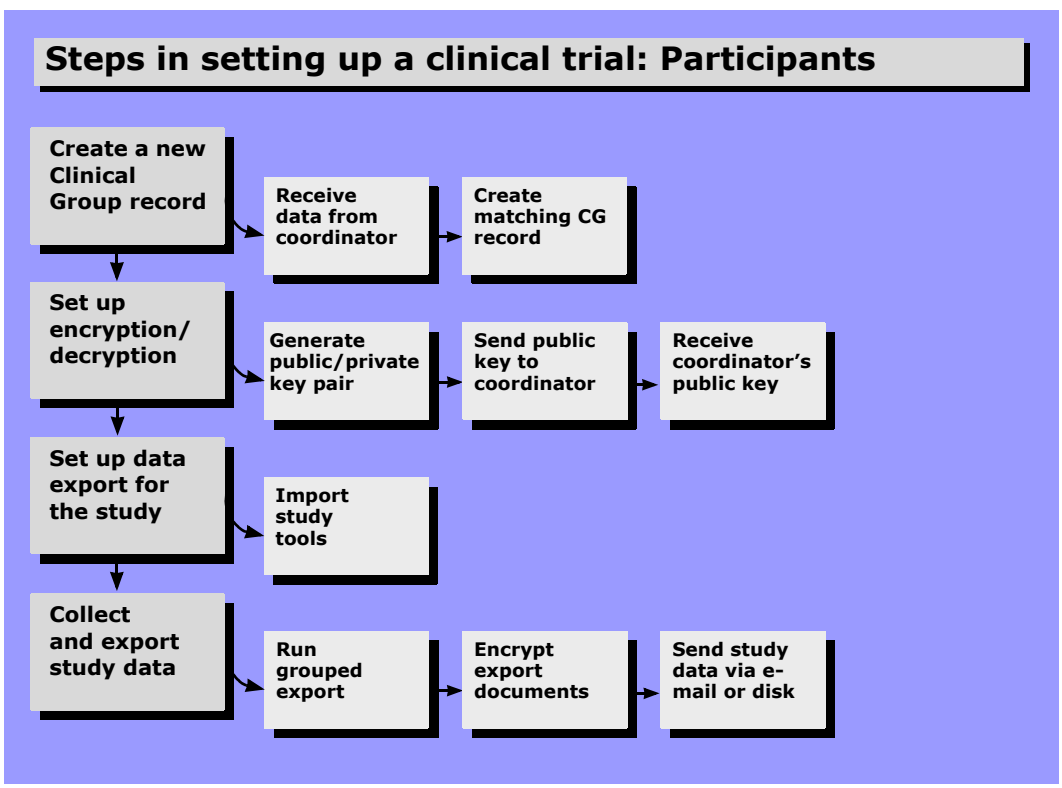
1. With the Clinical Group record open, select Clinical Group > Remove Subjects from Group from the menu bar.
   A Search for Subjects form opens.
2. Search for the set of subjects you wish to remove and drag it to the Drop Selected Subject Set.
   All subjects in the set are removed from the Clinical Group.

Steps for the participants

For participants, setting up a trial is a relatively simple process because the study coordinator has already performed many of the tasks. You will create a matching Clinical Group record, set up encryption/decryption, and import study tools. After that, taking part in a study is a process of collecting data and sharing it with the study coordinator using a number of different sharing options.

Here is a quick breakdown of the steps for a participant to set up a trial. For a visual overview, see the diagram below.

1. Create a new Clinical Group record.
    - Receive from the coordinator the information for the study's Clinical Group record: study name, unique list name, Study Participant ID, and (optional) coordinator's e-mail information.
    - Enter the data received from the coordinator into the Clinical Group record in your data file (see "Setting up the Clinical Group record" on page 21).
2. Set up encryption/decryption.
    - Generate public/private key pair (see "Setting up encryption" on page 23).
    - Send your public key to the study coordinator.



- Receive the coordinator's public key (see "Setting up decryption" on page 24).

3. Set up data export for the study
   - Use the "Import study tools" item on the Clinical Group Record menu bar (see Page 35).
4. Collect and export study data
   - Export study data as a Clinical Group Export (see "Exporting a Grouped Export" on page 36).
   - Encrypt export documents, which is performed automatically if you use a Grouped Export.
   - Send study data to the coordinator using Otobase's internal mail system, or via disk documents (see "Tips on using e-mail to export and import shared study data" on page 36).

Importing study tools

Participants who have received the public key from the coordinator and entered it in the Clinical Group form can import encrypted Checklist, Search and Export definitions into their version of Otobase using a single menu item. You should have received the OT3 file from the study coordinator, and placed it in a location that you can browse to during the process of importing the file.

To import the bundled Clinical Group Checklist, Search and Export

1. While logged on as administrator, open the Clinical Group record for this study and make sure it is unlocked.
2. On the Clinical Group menu bar, click Clinical Group > Import Study Tools.
   An Open dialog appears, allowing you to browse to the location of the OT3 file sent by the study coordinator.

   Note: If you are sharing the OT3 file between platforms.the normal Open dialog may not show the file. Hold down the shift key while selecting the Import Study Tools menu item to show all files.

3. Click Open.
   Otobase automatically imports and decrypts the group Checklist, Search and Export definitions.
4. You can verify the study tools have been imported by making sure the text on all three of the buttons under Checklist/Grouped Export on the form has turned to italics.
5. Save the Clinical Group record.
6. Assign Checklists to any Providers who will be entering data in the study (see "Assigning Checklists" on page 30).

Exporting a Grouped Export

For the purposes of sharing data in a clinical study, you can create a group of related records or subsets of their data fields pertaining to the study, and then export this data. This simplifies exporting for users in a clinical study and helps to ensure that data exported for the study is valid and complete. You or your study coordinator define the data fields that make up a Grouped Export using the Preferences form and then assign the Grouped Export to a Clinical Group (see "Creating a Clinical Group Export" on page 27 and "Assigning a Clinical Group Search and Export" on page 29).

Selecting the Export a Grouped Export item on the Administrator Menu Bar opens the form called Clinical Groups with Defined Exports.

The form displays a list of all Clinical Groups with defined exports. If you double-click on one of the groups, Otobase will execute the predefined searches for the records to be exported. In addition to selecting the appropriate Clinical Group for export, you can choose to export just the checksums without the actual data.

If you select the checksums option, Otobase will export the checksums in a TRANSFER-type document, which can be encrypted.

Selecting the Records option will add the records that make up a Grouped Export to a set of previously exported records. If you try to export the same records, you will see an Alert dialog reminding you that the records have already been exported. To export these records again, open the appropriate-Clinical Group form and select the Clinical Group > Erase Grouped Export Set menu item.

If the Clinical Group was designated as a study and if an encryption key pair has been assigned to the study, the export files will be encrypted automatically. In addition, if a study participant ID was assigned, it will be substituted in all ID fields (see "Assigning Study Participant IDs" on page 22).

Tips on using e-mail to export and import shared study data

When exporting a Grouped Export, you will be given the option of saving the grouped export documents as disk files or sending them via e-mail using the Clinical Group's e-mail address and attachment information. If the export documents are sent via e-mail, they will also be saved in a folder whose name is the date of the mailing (for example, "2_21_2002"). This folder will be found in the OTBEC folder, saved in various locations depending on your operating system. To find the path to the OTBEC folder, click Help > About Otobase (Windows) or Apple Menu > About Otobase (Mac) and select the Folder Info tab.

Otobase-generated e-mail can be identified by the e-mail subject line, which follows the format: "$OT2Doc_001UWMC..." You can copy any attached documents to disk using your e-mail program and import them from there, or Otobase can download the e-mail attachments directly.

To use e-mail importation, make sure your e-mail information is entered on your Provider form, or in the case of the Administrator, entered via the Administrator e-mail item on the Provider form.